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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,921	07/10/2002	Hiroshi Kido	2002-0319A	2978

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,921

Applicant(s)

KIDO ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/13/05 has been entered.

Claims 1- 5 are under consideration.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 5 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant's arguments and amendments overcome the rejection.

Rejections Maintained

Claim Rejections - 35 USC § 103

Claims 1- 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kido *et al.* and Christensen *et al.* in view of Robbins *et al.*

Applicant argues that Kido lacks the suggestion to use miniplasmin, let alone human miniplasmin in an assay, that Kido fails to disclose or suggest each and every element in the claimed invention, namely the use of MDCK cells and CIU in the screening method with human miniplasmin.

Applicant's arguments have been full considered and not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The rejection is based on obviousness, not anticipation.

Kido is aware of the specificities required of proteases to cleave influenza (see Table 1 and Figure 1). The use of CIU, MDCK cells and methods to determine infectious virus are known in the art and it is noted that Applicant argues that CIU is an art known term therefore the assay must be known; furthermore, Kido *et al.* disclose CIU (an assay to test proteases by reacting with a substrate virus and then infecting MDCK cells to determine infectivity page 237, column 1, last paragraph and Figure 3a).

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Also Kido et al. clearly suggest the human miniplasmin because in the section on miniplasmin (page 237, column 2) they indicate that trypase clara alone was not the only protease involved because inhibiting it was not sufficient to prevent activation of influenza and they clearly suggest that there is an agent in humans that has the same function (page 236, column 1, lines 15-18).

The argument that Christensen *et al.* does not teach the cleavage site is not persuasive. Kido et al. discloses the protease cleaves on the ARG. Robbins et al. teaches human plasmin and compares it to other plasmins including rat and notes no specificity differences (pages 198-199).

It would be obvious to one of ordinary skill in the art to look for the human functional equivalent of miniplasmin because one is looking for an inhibitor of influenza for use in humans. Christensen *et al.* is cited as evidence of human miniplasmin. One of ordinary skill in the art would be able to determine homologous proteins to rat miniplasmin and proteases with the requires cleavage specificity.

It would be prima facie obvious to one of ordinary skill in the art to modify the miniplasmin assay of Kido et al. with the human miniplasmin of Christensen *et al.* knowing the teachings of cleavage in Kido *et al.* and Christensen *et al.* and modify it based on the teachings of Robbins et al. with the expectation of success knowing that Kido *et al.* teach there is an additional protease to block to inhibit influenza and that Robbins et al teaches a human plasmin that is related to the rat plasmin of Kido *et al.*

Thus, the invention is not patentable over Kido *et al.* and Christensen *et al.* in view of Robbins *et al.*

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Conclusion


No claim is allowed.

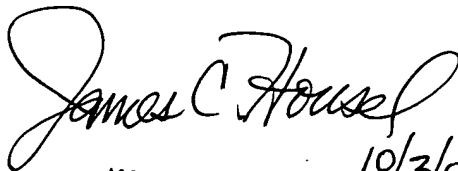
Lazarowitz et al. is cited as of interest that plasmin is well known in the art to cleave influenza HA proteins.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

Myron G. Hill 
Patent Examiner
September 14, 2005


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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10/3/05